

IMI2 Project 802750 - FAIRplus
FAIRification of IMI and EFPIA data

WP5 – Project management, dissemination and sustainability

D5.7 FAIRplus Handbook and project monitoring

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1. Executive Summary

This report provides an overview of the maintenance and review of the FAIRplus Project Handbook as well as the continued project monitoring activities between months 12-36 of the IMI2 JU FAIRplus project, including: Key Performance Indicators (KPIs), risk management, financial monitoring, project sustainability, and lessons learned.

2. Methods

As established during the early phase of the project (months 0-4) the FAIRplus Project Management Team (PMT), consisting of the Project Lead and Project Coordinator (Janssen and ELIXIR Hub respectively), have continued to work collaboratively to annually review the project handbook. The original Project Handbook, which was written using the PM² template¹ and previous knowledge from the Project Managers of managing IMI projects, was maintained as a living document, available to all project participants on the secure FAIRplus Google Drive. As and when project processes, guidance, or general information needed updating this was done on the fly, with a full annual review conducted during Q4 every year. Once the draft was complete and ready, it was circulated to all project participants for review and comment before suggestions were incorporated and feedback addressed to then have a final version of the handbook. This process was successfully completed in years 1, 2 and 3 of the project (months 12, 24 and 36).

In addition to the project handbook, using the methods devised by the Project Management Team early on in the project, we have tracked project Key Performance Indicators (KPIs) and project risks. These are monitored regularly and collaboratively and are reviewed every three months during the Managing Board teleconferences (TCs).

3. Results

The results have been outlined in the following subsections.

3.1. Project Handbook

The living Project Handbook is up to date as of 10th December 2021 and can be viewed in Appendix 1.

In Figure 3.1.1 (below) you can see the Table of Contents used in the Project Handbook which is adapted from the Open PM² template². The PM² Methodology

¹

[https://webgate.ec.europa.eu/fpfis/wikis/display/openPM2/Artefacts?preview=/175357231/351800464/\(OPM2-04.P.TPL.v3.0\).Project_Handbook.\(ProjectName\).\(dd-mm-yyyy\).\(vx.x\).docx](https://webgate.ec.europa.eu/fpfis/wikis/display/openPM2/Artefacts?preview=/175357231/351800464/(OPM2-04.P.TPL.v3.0).Project_Handbook.(ProjectName).(dd-mm-yyyy).(vx.x).docx)

²

[https://webgate.ec.europa.eu/fpfis/wikis/display/openPM2/Artefacts?preview=/175357231/351800464/\(OPM2-04.P.TPL.v3.0\).Project_Handbook.\(ProjectName\).\(dd-mm-yyyy\).\(vx.x\).docx](https://webgate.ec.europa.eu/fpfis/wikis/display/openPM2/Artefacts?preview=/175357231/351800464/(OPM2-04.P.TPL.v3.0).Project_Handbook.(ProjectName).(dd-mm-yyyy).(vx.x).docx)

originated from the European Commission and Open PM² provides many guidelines and templates to facilitate the management and documentation of EC projects.

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Figure 3.1.1. FAIRplus Project Handbook Table of Contents

3.1.1. Update of processes as defined in the Project Handbook

All project participants are welcome to, and actively encouraged to suggest updates to the processes which were defined in the first version (V1.0) of the Project Handbook. The Project Handbook was designed to be a living, adaptable resource and therefore,

as we refine and define new processes, the Project Handbook is updated to avoid it becoming stagnant and of no help to project partners. During the implementation phase of the Project Handbook, a significant number of updates were made to the originally defined processes between March and December 2019, this was due to working experiences of the project where the PMT quickly found out what worked and what didn't work. Those changes were listed in the first Project Handbook deliverable, D5.3 in December 2019. Since V1.0 was finalised in December 2019, the number of updates to processes significantly reduced as the project found its feet and processes became the established norms. The updates have been listed below:

- 1) A definition of the FAIR-CMM Team, Cookbook Editorial Working Group, FAIRification Wizard & FAIRtooling Teams have been defined
- 2) Distribution lists have been updated with newly created DLs
- 3) The reporting periods have been updated inline with the shifts caused by the 6-month, no cost extension (as a result of COVID-19)
- 4) The deliverable and milestone due dates have been updated inline with the shifts caused by the 6-month, no cost extension (as a result of COVID-19)
- 5) The description of the Squads has been updated based on process experience

3.2. Key Performance Indicators (KPIs)

Table 3.2.1. KPIs reflected on the FAIRplus site to demonstrate the impact of the project's work.

KPI TITLE	KPI DESCRIPTION
Fully exploit IMI project data to target advances in healthcare.	Increased FAIRness of >20 datasets from IMI/EFPIA projects to be measured using a CMMI assessment and the CMMI scale and recorded in the IMI catalog. FAIR metrics (determined in Task 3.1) will be used to iteratively evaluate our progress (Task 3.2).
Advances in drug discovery decision making such as target discovery, selection and validation.	Narrative examples from case studies of IMI project datasets in which the FAIRplus project has improved the FAIRness level.
Strong increase of expertise in the creation, curation, and stewardship of FAIR databases within IT communities.	External attendance at FAIRplus Innovation & SME Events – our target is 20 organisations/event, tracked by type of organisation and affiliation to FAIRplus.
Building skills and increasing competitiveness for SMEs in Europe.	SME collaboration: Attendance by SME personnel at FAIR Innovation & SME events
The project will have a significant impact on the scientific community regarding the broad adoption of FAIR data stewardship. This in itself will have a long-lasting value-adding impact on	Data usage, starting with IMI catalog (WP3) and tools usage; refined and improved metrics into public domain. Data from Google Analytics of the live FAIR cookbook site since 2020.

effective scientific data usage.	
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At the start of the project the Managing Board reviewed the list of Key Performance Indicators included in the Description of Action and identified which could be reported on.

These were added to the FAIRplus website on a dedicated dashboard page³ and updated periodically. The Squad Leads were responsible for collating the majority of the data required to update the dashboard; this they collected during their, roughly, quarterly F2F meetings (since March 2020 these 'F2F' meetings have been held virtually). The remaining data was collected by WP4 in a combination of communication and dissemination analytics and data from the University of Luxembourg who host the FAIR data catalog⁴. This data was then added to the KPI Dashboard document⁵ (stored on the FAIRplus Google Drive) which in turn, automatically updated the KPI Dashboard hosted on the project website.

The Dashboard itself was reviewed and updated in Month 18 as part of Deliverable 5.4 KPI Dashboard⁶.

In 2021, the dashboard was reviewed once again to meet the project's needs and reflect the evolving outputs of all Work Packages. Some KPIs were no longer adding value, or data was insufficient to extract conclusions. In January 2022, the revamped dashboard will be fully functional and available on the project website.

The new additions and changes will focus on:

- **Interactivity.** Tableau will be used to embed an interactive dashboard. The data will still be linked to a Google Drive Spreadsheet, which will ensure the automatic update of the KPIs shown on the FAIRplus site.
- **Open data.** Data showcased on the KPI dashboard does not currently allow access to the raw data from which the analysis and visualisation have been produced. Tableau Public enables the viewer to download non-sensitive raw data from a dashboard. Hence, making all our dashboard data freely available.
- **Impact.** The dashboard will showcase a storyline that explains the importance of each KPI. The ability to interact with the dashboard and select time ranges will also improve the impact story aspects of it by demonstrating the progress of FAIRplus work over time.

³ KPI Dashboard: <https://fairplus-project.eu/impact/kpi-dashboard>

⁴ IMI data catalog: <https://datacatalog.elixir-luxembourg.org/>

⁵ KPI Dashboard document:

https://docs.google.com/spreadsheets/d/1CPvfYBA6InfXCB_IHFCjKtfX5wX6OvWxwKAnoH6nWRc/edit?usp=sharing

⁶ D5.4 KPI Dashboard: <https://doi.org/10.5281/zenodo.3964434>

How much has the project progressed?

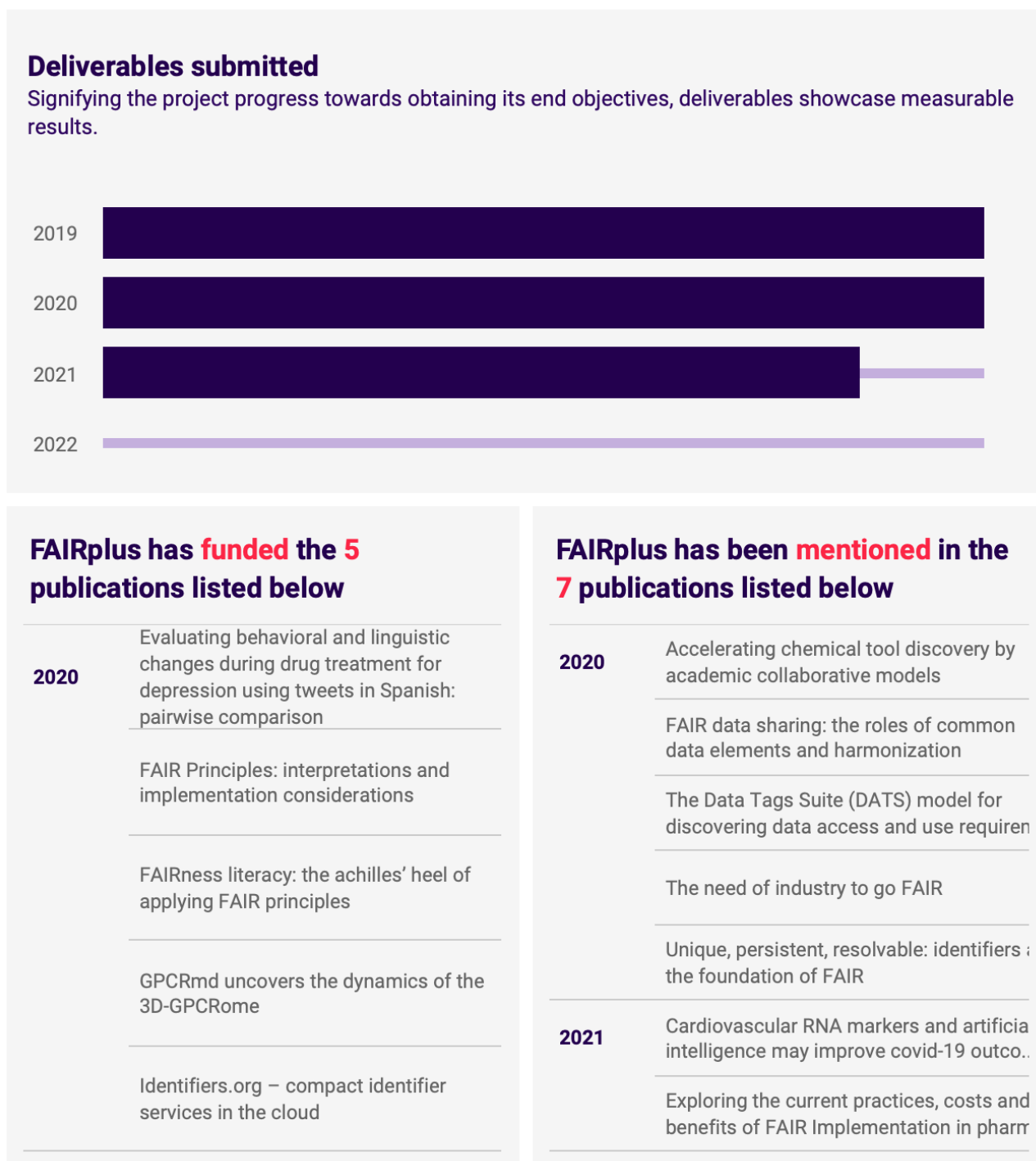


Figure 3.2.1. The KPI Dashboard.

The dashboard will be sustainable until the end of the project, and beyond, since it will be hosted on the ELIXIR Europe account in Tableau Public.

3.3. Governing Boards

The goals and responsibilities of each project board were formalised in the Consortium Agreement and detailed in Section 5: Project Management Structure and Responsibilities of the Project Handbook. Due to the COVID pandemic, there has been some disruption to the original meeting schedules (included in the Project Handbook), however, best efforts were made to maintain frequent involvement of the boards and despite setbacks, they have attended the required project meetings which were subsequently held remotely, as well as being on hand to provide input via email during Months 13-36.

3.3.1. Ethics Advisory Board (EAB) and Scientific and Industry Advisory Board (SIAB)

Following the FAIRplus kick-off meeting in January 2019, the EAB and SIAB were not required to attend project meetings during the first 12 months of the project as it was deemed their input would be more beneficial later in the project. As expected, both boards attended the Managing Board and General Assembly meetings during this later period and have been forthcoming and with their support via email interactions as and when required.

Of note, one of the SIAB board members, Johan van der Lei, retired at the end of 2019 and despite efforts to find a replacement board member, the decision was taken in September 2021 to not continue the efforts and complete the remainder of the project with 6 board members. This remains in line with the board member quota detailed in the project handbook which states we must have no less than five SIAB members and no more than nine.

3.3.2. Associated Partners Working Group (APWG)

In the project Description of Action and Consortium Agreement it was outlined that the APWG may be invited to some or all of the Squad team TCs at the discretion of the Squad team members and based on their needs. It was also stated that they may be invited to the Squad F2F meetings (known as Bring Your Own Data (BYOD) Workshops in the original DoA).

Early work by the Squad teams indicated that there was not a pressing urgency to have the APWG members attend the weekly meetings, or the periodic face-to-face meetings.

Additionally, an agreement would first need to be in place between the APWG members and the FAIRplus consortium before any of the APWG members could join the Squad meetings. While the APWG members were named in the DoA, having each provided an expression of interest, they were not party to the Grant Agreement and therefore, a CDA or Advisory Agreement would be needed before they were exposed to possibly confidential project information.

While neither of the Squad teams have identified a need to have any or all of the APWG members join their meetings to date, the required legal negotiations have not been prioritised by the project legal counsel. This has allowed the lawyers to focus their efforts on more pressing legal negotiations.

That being said, many of the APWG members attended the first two FAIRplus Innovation and SME Forums in January 2020 and remotely in January 2021 and for the final FAIRplus Innovation and SME Forums in May 2022 it is planned to use half of the event to focus on the APWG members with each invited to come and liaise with experts from FAIRplus and provide content for the FAIR Cookbook. The idea is that each of the companies would propose a recipe idea for the FAIR Cookbook and then work with a FAIRplus expert to solve this problem or address the suggested recipe. By using this approach for the event we will be able to show real outcomes of the project. Further we hope that this event format will prove useful for all companies engaged in the APWG.

3.4. Working Groups

3.4.1. Cookbook Editorial Working Group

Led by Philippe Rocca Serra, University of Oxford, the Cookbook Editorial Working Group coordinates content creation. This is done through several mechanisms:

- 1) Discussion among Editors (Wei Gu, University of Luxembourg; Tony Burdett, EMBL-EBI; Susanna Sansone, University of Oxford; Andrea Splendiani, Novartis AG; Robert Giessmann, Bayer AG). This method corresponds to a top-down approach where editorial lines are decided and topics developed based on scientific and technical insights from the editors.
- 2) Community outreach: typically performed via interactions with ELIXIR Europe, the Pistoia Alliance and the FAIRplus EFPIA partners, but also the Alan Turing Institute.
- 3) Requests from the FAIRplus SQUADS: As new IMI projects are recruited, new FAIRification scenarios are considered and some bring up new use cases, which in turn, leads to new documentation and material around that theme to be produced.
- 4) Engagement with the FAIRplus Fellows: Use cases and problems put forward by the fellows to the FAIRplus experts.

Points 2, 3 and 4, above, represent the bottom-up approach to content development.

From an operational standpoint, the Cookbook Working Group meets fortnightly and organises the monthly Bookdash events. During these one-day events, contributions are consolidated and tickets and github issues are sorted, prioritised or resolved. Recipes reaching production status are assigned a stable identifier and released.

A github discussion functionality has also been activated in addition to the dedicated mailing list and slack channel.

3.4.2. FAIR-CMM Team

Led by Ibrahim Emam, Imperial College London, the FAIR-CMM team is responsible for delivering the FAIRplus data maturity framework, which aims to act as a guide to advance the cause of FAIR data within the IMI office, IMI projects, and EFPIA partners. This is achieved through the development of a new FAIR dataset maturity model that demonstrates the benefits of stepwise FAIR advancement and how to reach different levels of maturity.

The team runs a weekly ‘Development’ meeting, which focuses on developing the different components of the framework according to the team’s laid out plan. Another ‘Feedback and Review’ meeting runs monthly with a wider audience that also includes interested parties amongst the FAIRplus EFPIA and academic partners. During these meetings they review the progress and provide feedback on the interim outputs.

Engagement with the SQUAD team. The FAIR-CMM team lead is also a member of the SQUAD team leads, which helped establish early alignment between the SQUAD’s FAIRification process and the development of the FAIRplus data maturity process. The FAIR-CMM team also actively participates in the Squad ‘Face-to-Face’ meetings for a wider engagement and outreach.

3.4.3. FAIRification Wizard Team

Led by Fuqi Xu, EMBL-EBI, the FAIR Wizard connects recipes from the Cookbook and assessment approaches from the FAIR-CMM team and integrates the Squads FAIRification actions. It guides users to find FAIRification technical solutions based on their use cases. It is developed through collaboration from EMBL-EBI and the FAIRplus consortium.

Software development: The development of the FAIR Wizard is led by EMBL-EBI (Isuru Liyanage, Tony Burdett, Melanie Courtot, and Fuqi Xu). The source code is published in Github⁷ under Apache 2.0 license. Github issues have been used to discuss, track and prioritise the tasks in an agile manner.

Development within FAIRplus:

- The squads teams provide use cases, FAIRification expertise and review feedback for the FAIR Wizard in weekly Squad meetings.
- Monthly reports on the development progress in the Work package 2 and 3 meetings
- The FAIR Wizard developers join the weekly Cookbook meetings, monthly Cookbook Bookdash, as well as monthly FAIR-CMM meetings to ensure work from different teams are aligned.
- EFPIA partners and IMI projects that collaborate with FAIRplus are the primary target users and provide feedback to the FAIR Wizard.

⁷ https://github.com/FAIRplus/FAIR_wizard/

Outreach: The FAIR Wizard development team also collaborates with external projects, such as the Human Cell Atlas to integrate FAIRification resources from multiple sources and cater to various use cases.

3.4.4. FAIRtooling team

Led by Fuqi Xu, EMBL-EBI and co-contributor, Eva Martin Del Pico, Barcelona Supercomputing Center. The FAIRtooling team aims to provide tooling solutions for different FAIRification operations, as well as a tool discovery software to facilitate the identification of FAIRification tools.

Development: Weekly updates during the Squad meetings and monthly development meetings. Plus, ad-hoc meetings with EFPIA and IMI project partners. The mailing list, fairtooling@elixir-europe.org, has been used to connect members from EFPIA, IMI projects and the Squads. The source code is published in Github⁸ under Apache 2.0 license.

Community outreach: The FAIRtooling discovery software uses ELIXIR resources such as Bio.tools and EDAM ontology. It also integrates tool collection and review results from the OpenEBench project.

3.5. Project output monitoring - deliverables, milestones and tasks

At month 15 of the project we were hit by the COVID-19 pandemic and over the next 20 months many project partner organisations and individual participants found themselves significantly and negatively impacted by the pandemic. To date, impacts have included (but are not limited to):

- Lockdowns in multiple countries
- Roles and responsibilities amended to meet the needs of the pandemic:
 - Scientific research refocused on the pandemic response
 - Roles changed to work or volunteer in hospitals, surgeries etc.
 - Teaching roles being impacted significantly due to the need for remote teaching and/or increased teaching workload
 - Caring duties including, but not limited to, homeschooling needs and care for elderly or vulnerable relatives
 - People suffering burnout and/or departments where multiple colleagues are suffering burnout or are working on other things and with others left to 'pick up the slack'
- Meetings and events not taking place as planned. The FAIRplus project was planned around a series of face to face meetings, events and training:
 - Formerly known as BYODs and now known as Squad meetings, since the start of the pandemic these 2-3 day meetings have had to be held remotely via Zoom

⁸ https://github.com/FAIRplus/WP3_FAIR_tooling

- The last Innovation and SME Forum was held remotely and was a success for this format, but greater impact will be achieved if we can hold the next and final Innovation and SME Forum F2F
- The Fellowship Programme planned to provide training to FAIRplus Fellows during F2F lessons both in ‘class’ and in a shadowing/mentoring format. While much of the Programme has now been planned for remote learning, real value will be gained from holding the last modules F2F
- Policy maker engagement; a series of F2F meetings with key stakeholders were planned followed by a Brussels-based event; this had to be held via Zoom
- During the last year, the following meetings have been held remotely rather than F2F as planned:
 - The 5th Squad ‘F2F’ meeting which should have run 28-30th April in Barcelona
 - The subsequent 6th, 7th, 8th and 9th Squad ‘F2F’ meetings
 - The Managing Board/EAB/SIAB meeting, 21st July 2020 in Utrecht
 - MTR, 9th October, IMI, Brussels
 - General Assembly, January 2021, Berlin
 - Innovation and SME Forum, January 2021, Berlin.
- During the last year, the following meetings and activities have been delayed due to the impact of the pandemic:
 - FAIRplus: What is the value of FAIR data? Stakeholder and policy maker outreach event, 9th December 2020 - should have been held in Brussel in October, delayed to December and then moved to Zoom
 - Launch of the Fellowship Programme
 - 9th Squad ‘F2F’ meeting, scheduled to be held remotely in February but pushed to April as Squad work has slowed during Q1 2021 specifically caused by the most recent lockdowns.
 - 10th Squad ‘F2F’ meeting, scheduled to be held remotely in November but pushed to December
- During the last year, the following meetings have been cancelled due to the impact of the pandemic:
 - Managing Board, SIAB and EAB meeting scheduled for 14th January 2021.

To mitigate the impact of the pandemic on the project, a six-month, no-cost extension was requested and approved by the IMI. In addition to the benefits which will be felt by hosting some of the outstanding meetings and events face to face during the six-month extension, it also allows the Work Packages time to postpone deliverables. Many, if not all tasks have slowed during the pandemic due to the various reasons outlined above. Without the extension it would have meant project results detailed in the remaining deliverables would not have been to the standard we were aiming for; work simply wouldn’t be completed on the work package tasks.

The reporting periods are now:

- RP1: M1 - M18 (18 months) 01/01/19 - 30/06/20
- RP2: M19 - M37 (18 months) 01/07/20 - 31/12/21
- RP3: M37 - M48 (12 months) 01/01/22 - 31/12/22

The deliverables impacted by the pandemic and with amended due dates are:

- D1.4 Finalised selection criteria and guidelines for data sources taking into account practical operational experiences established within WP2 and WP3 (Fraunhofer). Moved from M36 to M42
- D2.1 FAIR Cookbook (UOXF) Moved from M36 to M42
- D2.2 BYOD Squads Guidelines (UNIMAN) Moved from M36 to M42
- D3.4 First EFPIA participant FAIRification complete (EMBL-EBI) Moved from M30 to M36
- D3.6 Provide a technical feasibility report (EMBL-EBI) Moved from M36 to M42
- D3.7 A FAIRification guidance tool for IMI (PHACTS) Moved from M36 to M42
- D3.8 Sustainability White Paper (EMBL-EBI) Moved from M36 to M39
- D4.5 Use case dissemination package (LYG) Moved from M36 to M42
- D2.6 FAIR-CMM (ICL (see below in AT21)) Moved from M42 to M48
- D5.8 FAIRplus overview of the scientific publications (ELIXIR Hub) Moved from M42 to M48

The milestone impacted by the pandemic and with an amended due date is:

- M1.2 Journal publication describing finalised selection criteria and guidelines for data sources taking into account practical operational experiences (AZ). Moved from M30 to M36.

3.5.1. Deliverables

The status of those deliverables upcoming for the next 12 months are reviewed monthly during the WPLs TC.

A deliverables tracker is stored on the FAIRplus Google Drive in the project master file and as soon as a public deliverable is submitted to IMI2 JU it is simultaneously published on Zenodo and linked to from the FAIRplus website on the dedicated Deliverables and Milestones page⁹.

3.5.2. Milestones

As with the project deliverables, the status of those milestones upcoming for the next 12 months are reviewed monthly during the WPLs TC.

A milestone tracker is stored on the FAIRplus Google Drive in the project master file.

By the time this deliverable report (D5.7) is submitted to IMI, all FAIRplus milestones will have been reached.

⁹ <https://fairplus-project.eu/about/deliverables>

3.5.3. Tasks

A list of all tasks and sub-tasks, as defined in the Description of Action, is kept updated in the project master file which is stored on the dedicated FAIRplus Google Drive. Against each task and sub-task we have listed a (sub-)task lead and the (sub-)task team. These tasks are reviewed and tracked by the corresponding work package during their monthly Work Package TCs and any identified and related risks are brought to the attention of the Managing Board during their monthly TCs.

In addition, the two Squads teams, which comprise members across the work packages, work towards the same tasks and (sub-)tasks but also have their own defined tasks per Squad. The Squads use a GitHub repository to assign and update tasks against each team member. Again, a progress check is conducted during the weekly TCs. In addition, the Squad leads meet monthly to discuss the progress of the Squad teams and work to find mitigation measures in instances where tasks are not on track and/or bring a status update to the Managing Board meeting every month.

3.6. Risk Management

In Tables 3.6.1 and 3.6.2, below, the state of play for Period 1 remains the same as previously reported and Periods 2 & 3 have been populated. In addition, Table 3.6.3. has been included where we identify potential new risks and the planned mitigation.

Table 3.6.1. Status review per risk

RISK #	Description of Risk	WP	Proposed Risk Mitigation	State of Play		
Period 1						
				Mitigation applied?	Did risk materialize?	Comment
1	Delay in or failure of recruiting suitably qualified personnel for the assigned effort and access to skills in data science	WP1, WP2, WP3, WP4, WP5, WP6	Monitoring of recruitment by the Project Leader and MB during project start-up; Possibility of joint recruitment (e.g. Shared advertisement)	From efpia side: all partners have engaged their transcriptomic data experts and provided input offline or during squad F2F	no	Full buy-in and strong interest of pharma to squads

2	Failure of effective management of a large consortium consisting of academic participants, large industry and SMEs.	WP5	FAIRplus consortium and project management will build on established ELIXIR Hub and Janssen project management practice and experience in managing large international consortia; Ensure that the WPL group (MB) function effectively with regular, standardised reporting; Ensure that roles and responsibilities are clearly defined and plans align with overall strategy (MB); Establishment of Squad teams to drive an efficient work flow across WP; Establishment of an Ethics Board.	Communication gap bridged	yes	Much more alignment between ongoing activities, deliverables and participation
3	Inappropriate level of engagement of EFPIA participants.	WP1, WP2, WP3, WP4, WP5, WP6	Provide clear paths for engagement and utilisation of in-kind contribution (i.e. BYOD, fellowships) to facilitate an effective and efficient collaboration and workflow. Develop early understanding of needs and requirements of EFPIA participants. Review engagement periodically to apply remedial action.	At risk until May 2019	<ol style="list-style-type: none"> 1. EFPIA TCs and invitation to participate in July F2F at Lilly 2. requirements gathering 	Due date delivery of input to the squads

4	Failure of the negotiations on the exit of the United Kingdom from the European Union to secure participation in EC research programmes puts funding for UK participants at risk.	WP5	Project management will closely monitor the progress of negotiations and follow advice from UK Research Councils. The Joint Report (8 Dec,2017) states: Following withdrawal from the Union, the UK will continue to participate in the Union programmes financed by the MFF 2014-2020 until their closure [...] Entities located in the UK will be entitled to participate in such programmes. [...] funding for UK participants and projects will be unaffected by the UK's withdrawal from the Union for the entire lifetime of such projects Nevertheless, risk to delivery may remain and this will be monitored as part of on-going WP activities.		No	
5	Delays in sharing and managing access controlled human data due to varying GDPR implementations in member states and establishment of new policy practice.	WP1, WP2, WP3, WP4, WP5, WP6	Project will closely monitor GDPR implementations and practices for research data sharing (WP1 & 5) and establish guidelines (WP1, 2 & 5). All WPs will manage data that falls under GDPR (e.g. user identities) WP1 will proactively have dialogue with IMI project and institutional data protection officers. GDPR risks are actively monitored by participants as part of their own ongoing operations today. Budget is allocated for external legal support.		NO	Looking into clinical data sharing processes identified in IMI_ ABIRISK can bring lessons learned to FAIRplus

6	Data security breach	WP3	Required as a continuous process for computational resource providers: Improvement of the security practices based on risk management (e.g., conducting audits, escalation routines, implementation of AAI).		NO	
7	Late access to IMI data	WP1	<p>Pilot projects will be selected in WP1, with a provisional potential group already established, to test processes that will promote early and adequate interaction with IMI and EFPIA participants to approve access to data. Engage WP1 participants providing legal expertise as required. Prioritise early access to data accessible to consortium members from pilots (Table 1).</p> <p>Progress will be checked at the bi-weekly FAIR-CMMI team meetings to monitor and react promptly in case of delays.</p>	Potentially present risk	Each EFPIA partner has reached out to internal colleagues in the lead of the listed IMI projects	The aim is to have agreement to access 10 IMI projects by Dec 31st 2019
8	Failure to complete the FAIRification of 20 IMI projects.	WP1, WP2, WP3, WP4	Develop capacity to enable data experts from EFPIA and IMI projects to FAIRify their own datasets via method, process, tools, knowledge and training made available by FAIRplus. Use expert knowledge of the IMI projects FAIRplus participants have previously participated in if engagement is limited for new projects. Pilot projects are expected to cover most of the data types, ensuring gaps on tools (if any) are identified. Progress will be checked at the weekly Squad meetings to monitor and react promptly in case of delays.	Communication gap analysis was performed and this risk is monitored actively	Possible	To set priorities, between EFPIA and squads. functional requirements have been extended (column H). This should provide concrete things to work on for the squads and should allow to find more overlap between use cases. We should make sure the

						squads understand that the requirements are data independent, even though the use cases were often formulated with transcriptomics data in mind.
9	Lack of balance between existing IMI project data exemplars and EFPIA participant needs/expertise.	WP1, WP3	Determine prioritisation across EFPIA participants (via WP1) and align IMI exemplars with EFPIA expertise/needs. Review quarterly to mitigate risk. Define >1 EFPIA participant per exemplar to reduce risk.		NO	
10	Impossibility to acquire KPI data.	WP5	Identify alternative KPI for the performance indicator affected that can be easily acquired and measured.		NO	
11	Lack of engagement from APWG.	WP2, WP4, WP5	Monitor level of engagement of APWG via participation in Squad and project meetings (e.g. BYOD).	Special Mutual CDA set in place by coordinator and project lead legal departments	YES	CDA to be shared with full consortium for distribution to all legal departments by Dec 15th 2019
RISK #	Description of Risk	WP	Proposed Risk Mitigation	State of Play		
Period 2						
				Mitigation applied?	Did risk materialize?	Comment

12	Practical solution for personal data is a huge challenge compared to preclinical data implementations score - expert system for project applications	WP6, WP5, WP1	Clinical data equals big value. Data sharing agreements are forming bottleneck: ELSI implementations score - DMP and sustainability	NO	YES	Risk of continued lack of full range of datatypes on clinical trial/ datasets - too few project outputs are released and clinical
13	Looking too much at the problem from data processor perspective	WP1, WP2, WP3	The value and needs are to look at the FAIRification from the data reuse perspective. FAIRplus can FAIRify the data that come in to their hands but that is not per se what the user needs.	No	YES	
14	Dissemination and communication strategy lacking.	WP6, WP5	Risk/challenge we are not reaching the companies and other beneficiaries with only a few proper success stories.	YES	NO	FAIRplus comms team expertise and daily effort
15	Unable to validate the impact of the FAIRification - KPI's identified	WP1, WP2, WP3	Consistent updates and continued monitoring by the Squads of the KPI dashboard.	YES	YES	Dashboard is updated frequently. Wider impact metrics of this dashboard is harder to quantify
16	Potential financial deviations	WP5	Conduct project governance and monitor budget and risks	YES	NO	Monitor and share overview in General Assembly
17	Sustainability project data management	WP1, WP2, WP3, WP4, WP5,	Project governance team actions and cross-work package with beneficiary	NO	NO	Strong focus on the topic based on MTR comments

18	End up with a formal “tick the box” 1 pager that is not meeting the needs for potential customer	WP1, WP2, WP3, WP4,	Cross work-package activities in Squads, Cookbook team and CMM	NO	NO	
19	Data processing agreement (cross-consortium agreement)	WP1, WP5,	Strong involvement from different legal departments within the various beneficiaries and management board (+legal) of the projects to engage with	NO	YES	Anticipating on legal agreement and negotiation progress
20	Insufficient participation in Fellowship Program	WP4	Focussed campaign	YES	NO	Strong campaign
21	Stakeholder interaction plan: where do we want to focus on as FAIRplus?	WP4/ WP5	Risk of missing opportunities because of the large and fragmented data science landscape	NO	NO	

Table 3.6.2. Status review per risk update **Period 3**

RISK #	Description of Risk	WP	Proposed Risk Mitigation	State of Play		
Period 3						
				Mitigation applied?	Did risk materialize?	Comment
12	Practical solution for personal data is a huge challenge compared to preclinical data: clinical data is big value	WP6, WP5, WP1	Focussed interaction on project with IMI preclinical datasets→ avoid Steering towards “less GDPR compliant” dataset inclusion	YES	YES	Strong involvement from different legal departments at the beneficiaries site

13	Looking too much at the problem with data processor perspective	WP1, WP2, WP3	The value and needs focussed on looking at the FAIRification from Data Reuse perspective	YES Reflected in the recipes. In the early stages, the recipes were closely tied to the specific needs of the project	YES	Hands-on work on datasets in cross-WP activities helped understand the value and needs towards data reuse
14	Dissemination and communication strategy lacking. Risk/challenge not reaching the companies and other beneficiaries with a few proper success stories	WP6, WP5	Dedicated efforts from WP4 and WP5 with communication strategy	YES	YES	WP4 and WP5 to look at the challenge and create solution on involving expert resource
15	Unable to validate the impact of the FAIRification (adoption by others)- KPI's identified	WP1, WP2, WP3	KPI dashboard: consistent updates and continued monitoring by Squads	YES	YES	Additionally, KPI data review during the virtual F2F meetings
16	Financial deviations	WP5	Conduct project governance and monitor budget and risks - resource and personnel delegation	YES	YES	Monitoring closely between scientific project lead and academic coordinator where any deviation occurs
17	Sustainability project data management	WP1, WP2, WP3, WP4, WP5, WP6	Project governance team actions and cross work with beneficiary- MTR comments. Risk of ending up with a formal "tick the box" 1 pager that is not meeting the needs for potential customer	YES Cross work package activities in Squads, Cookbook team and FAIR-CMM	YES Cookbook bookbash events frequently take place with experts to write new recipes for	Project governance team actions and cross work with beneficiary and external partners (eg Pistoia)

					the Cookbook based on their experience	Alliance,..)
18	Special CD&CA	WP1, WP5,	Strong involvement from different legal departments at beneficiary sites and management board of the projects to engage with	YES	YES	Strong liaison with WP1 and continued follow up on engaged external projects-
19	Insufficient participation in Fellowship Program	WP4	Focussed campaign	YES	YES	WP4 and Comms team have successfully achieved strong participation of Fellows from across the globe to the program with a targeted advertisement campaign that attracted a group of enthusiastic and involved Fellows. This risk can now be closed.

20	Stakeholder interaction plan: where do we want to focus on as FAIRplus? It is quite a busy landscape.	WP4/ WP5	Risk of missing opportunities because of the large and fragmented data science landscape	YES	YES This is a real risk that we try to overcome by focusing on the tangible themes for FAIRplus, in particular the dissemination of the Cookbook which is a priority for the project.	Liaise with other WPs and codrive visibility of FAIRplus alongside explorative actions to engage with collaborative players in the field eg Pistoia
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Table 3.6.3. New Risks identified and mitigation

RISK #	Description of Risk	WP	Proposed Risk Mitigation	State of Play		
Period 3						
				Mitigation applied?	Did risk materialize?	Comment
21	Risk of continued lack of full range of datatypes on clinical trial / datasets that form bottleneck	WP5, WP1	Try to engage with wide spectrum of IMI project datasets and assets and be pivotal in the development of the legal agreements to share and collaborate on sensitive data	YES	YES	Get hands on more project outputs released via (clinical) data sharing agreements.

3.7. Financial monitoring

Since month 12 of the project, financial monitoring has been conducted every six months as follows:

M12: internal project monitoring

M18: reporting to IMI

M24: internal project monitoring

M30: internal project monitoring

M36: reporting to IMI - due to open 1st Jan 2022

For all internal financial monitoring sessions, project partners were requested to provide their financial reporting data up to the end of the applicable period e.g. monitoring conducted at M24 covered the period M19-M24 and monitoring at M30 covered the period M25-M30. In each instance, the data received was collated with the data already on file and compared to the forecast based on pro-rata'd utilisation. While, as to be expected, all academic and SME partners provided their financial data, not all EFPIA partners could fulfil this request as they are not formally required to do so. However, many of the EFPIA partners were able to share with us the data reported to IMI during their annual report and/or were able to give us an indicative idea of whether they were on track or not, allowing us to build an overall picture of resource utilisation.

The data received was then analysed by the Project Coordinator to identify any over or under utilisation or deviations from the DoA and the findings were sent back to the individual partners concerned for their feedback or reasoning. Once these comments were again collated, the data was shared with the Managing Board during the next monthly meeting.

By conducting this activity every six months we have been able to identify early on and track any budget utilisation deviations and possible associated risks and find ways to mitigate these within the project. We will continue the financial monitoring activity until the end of the project with the next monitoring activity falling within the 2nd periodic reporting session to IMI.

3.8. Sustainability

Sustainability planning was more formally addressed following year one of the project, culminating in a plan that was delivered at M24 (D5.5¹⁰) and a white paper which will be delivered at M39 (D3.8).

Sustainability is integral to this project. As there is no knowledge of future funding that would align with or be a full extension of FAIRplus, it is deemed unlikely that funding at the scale of this project will be available to continue activities. Therefore, as described in D5.5¹¹, a methodical approach has been taken to identify and assess FAIRplus outputs & assets that have the maximum value for the wider community and highest potential for reuse. For these outputs a specific sustainability plan has been devised and published (e.g. for the FAIR Cookbook (WP2/3), the Capability Maturity Model (CMM) (WP2/3), the FAIR Fellowship Programme (WP4) and the framework on ethics, data and legal implications of data (WP6)). Three tiers were created to express and summarise the current stage of sustainability of each of these outputs:

- 1) Limited solutions found, resourcing unknown, long term partners unknown
- 2) Solutions are in progress, some resourcing options in discussion, long term

¹⁰ D5.5: <https://zenodo.org/record/4354652#.Yanlpi-l30p>

¹¹ D5.5: <https://zenodo.org/record/4354652#.Yanlpi-l30p>

- partner options under consideration
- 3) Solutions planned and implemented, resourcing in place and long term partners defined

The plan is now in an implementation phase and is under continued review by the WPLs with progress made to achieve the plan. As an example, the FAIR Cookbook¹², a resource that is considered essential to sustain beyond the project duration, has been included in the ELIXIR-UK and ELIXIR-Luxembourg Node Service Delivery Plans. Even though neither Node has funds at this moment in time to sustain the FAIR Cookbook beyond the duration of the project, this is a step in the right direction.

More generally, to build a user base for outputs or encourage reuse, FAIRplus has taken an open approach wherever possible. Using the FAIR Cookbook as an example, the guidelines ('recipes') will be open and sustained in a GitHub repository for the course of the project at a minimum. This supports long term sustainability as the recipes will be used and implemented by others beyond the project end date, as well as the encouragement and process for others to contribute extensions to existing and new recipes. During the course of the project, a comparison of different repositories will be made to ensure FAIRplus selects the most sustainable option.

In addition, the sustainability of our FAIR processes and methodology is under continuous consideration via the Squad teams, the most obvious example being when data types are matched to available hosting solutions eg. public repositories.

Wherever possible, FAIRplus uses infrastructure that is of a sustainable nature itself. As an example, ELIXIR is a sustainable infrastructure with long term funding from its Member States. The ELIXIR-Luxembourg Node Service Delivery Plan¹³ includes the "Translational Medicine Data Catalog (TMDC), which includes the IMI data catalog¹⁴ that is used in FAIRplus. The budget for maintaining the service will be covered by their structural (long-term) funding after the FAIRplus project.

The formal sustainability plan considered feedback from all WPLs, experience from other projects and has been discussed at many of our meetings including the 2021 General Assembly meeting. As another example, the plan, including financial models, was discussed at the Innovation & SME Forum in M25, with a panel that includes experts from other projects that have faced similar challenges (e.g. IMI OpenPhacts and Open Targets). The imminent white paper that will describe sustainability paths and strategies for adoption of FAIRplus tools and services will complement the formal sustainability plan but also can be used to more broadly discuss the challenges in this field and some initial learnings from the project during the FAIRification approaches.

To note, the aim of the FAIRplus project has always been to demonstrate the potential for increased data sustainability once it has been made FAIR. Individual sustainability per data source remains the responsibility of producers and consumers.

¹² FAIR Cookbook: <https://github.com/FAIRplus/the-fair-cookbook>

¹³

https://elixir-europe.org/services/list?field_scientific_domain_tid=All&field_elixir_badge_tid=All&field_type_of_service_tid=All&field_elixir_node_target_id=2299&combine=

¹⁴ IMI Data Catalog: <https://datacatalog.elixir-luxembourg.org/>

3.9. Lessons learned

The main and significant lesson learnt since month 12 of the project is:

- 1) Be adaptable to change - it could not have been anticipated that the world would face a global pandemic but the project and its partners have been resilient and have been willing to adapt as needed. Because of that flexibility, the project remains on track to deliver the original objectives as defined in the Description of Action.

4. Conclusion

The last 20 months have been challenging for FAIRplus, the beneficiaries involved and each and every participant. COVID has impacted us in ways we could not have foreseen when planning this project, yet at the end of our third year, with the help of a six-month no-cost project extension, we remain on track to fulfill all the project objectives.

We plan for 2022 to be the year we can meet face-to-face again during our General Assembly, third and final Innovation and SME Forum, Fellowship Programme meetings, and Squad meeting among other; but, if that is not feasible due to the pandemic then we now have the experience and infrastructure in place to hold successful hybrid or fully virtual meetings.

During the start of 2022 we will submit our second periodic report, however, having performed frequent, internal project monitoring we do not expect any major deviations or surprises.

The project website will continue to be maintained and will be used as a hosting platform for more project outputs including the recommended FAIRness levels - which have already been provided to IMI with the possibility of these being used in the guidance for future IHI JU call text - the FAIR-CMM outputs, the FAIR Wizard and the evolving KPI Dashboard.

Finally, project sustainability will be a continued focus during the last year of the project to ensure, hopefully, the maintenance of the core project outputs including the FAIR Cookbook, FAIR-CMM, and the Fellowship Programme.

5. Repository for primary data

All project documentation is stored on the private FAIRplus Google Drive. If you wish to access anything referenced in this deliverable report, please contact fairplus-pm@elixir-europe.org stating your need for access.

Appendix 1: FAIRplus Project Handbook V2.0

The Project Handbook is accessible to all project Partners on the private FAIRplus Google Drive:

[FAIRplus Project Handbook Living Document](#)¹⁵

¹⁵ <https://docs.google.com/document/d/1bxyhGsKYsVpYSmFCUKrGDFpO2T9tOKL8ZSHOgA16CB8/edit>